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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------|-----------------|----------------------|---------------------|------------------|
| 10/535,733 | 05/20/2005 | Osamu Ohara | 1254-0282PUS1 | 2831 |
| 2292 | 7590 07/09/200° | EXAMINER | | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 | | | GUSSOW, ANNE | |
| FALLS CHURCH, VA 22040-0747 | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 07/09/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | Application No. | Applicant(s) | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|--|--|--|
| | 10/535,733 | OHARA ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Anne M. Gussow | 1643 | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the | correspondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be form will apply and will expire SIX (6) MONTHS from cause the application to become ABANDON | DN. timely filed m the mailing date of this communication. IED (35 U.S.C. § 133). | | | |
| Status | • | | | | |
| 1) Responsive to communication(s) filed on 15 M | ay 2007. | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | This action is FINAL . 2b) This action is non-final. | | | | |
| .— | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 4 | 15 ₃ O.G. 213. | | | |
| Disposition of Claims | | | | | |
| 4) ⊠ Claim(s) 1,2 and 4-21 is/are pending in the approach 4a) Of the above claim(s) 6-17 and 20 is/are with 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1,2,4,5,18,19 and 21 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or | thdrawn from consideration. | | | | |
| Application Papers | • | | | | |
| 9) The specification is objected to by the Examine | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ acce | · | | | | |
| Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct | * | • • | | | |
| 11) The oath or declaration is objected to by the Ex | • | · | | | |
| Priority under 35 U.S.C. § 119 | | • | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applica rity documents have been received in Received. | ation No ved in this National Stage | | | |
| Attachmant(s) | | | | | |
| Attachment(s) 1) ☐ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/19/07. | 4) Interview Summai Paper No(s)/Mail 5) Notice of Informal 6) Other: | | | | |

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DETAILED ACTION

1. Claims 1, 2, 4, and 18 have been amended.

Claim 21 has been added.

Claim 3 has been cancelled.

Claims 6-17 and 20 remain withdrawn.

- 2. Claims 1, 2, 4, 5, 18, 19, and 21 are under examination.
- 3. The following office action contains NEW GROUNDS of rejections.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on March 9, 2007 was filed after the mailing date of the first action on the merits on January 17, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included in the mailing of this office action.

Objections Withdrawn

5. The objection to the specification is withdrawn in view of applicant's amendment to the specification.

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Rejections Withdrawn

6. The rejection of claims 1-3, 18, and 19 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn in view of applicant's amendments and cancellation of the claims.

7. The rejection of claims 1-5 and 18-19 under 35 U.S.C. 112, first paragraph as lacking enablement is withdrawn in view of applicant's amendment to the claims and arguments.

Inamori, et al. (Journal of Biological Chemistry, 2003. Vol. 278, pages 43102-43109) teach an assay for N-acetylglucosaminyl transferase activity (see GnT assay page 43105) which would allow one of skill in the art to screen proteins for N-acetylglucosaminyl transferase activity. Additionally, the amendment to claim 1 to recite "deletion, substitution, or addition of within one to twenty amino acids" in a protein of more than 700 amino acids, as is SEQ ID No. 2, results in a more than 95% identity to SEQ ID No. 2 when the maximum of twenty amino acid residues are changed. This, in combination with the assay for specific activity of the protein would enable one of skill in the art to make the protein as claimed.

8. The rejection of claims 1-3 and 18-19 under 35 U.S.C. 101 as being directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims.

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9. The rejection of claims 1-5 and 18 under 35 U.S.C. 102b as being anticipated by Sanjanwala, et al. is withdrawn in view of applicant's amendment to the claims.

Response to Arguments/NEW GROUNDS OF REJECTION Claim Objections

10. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 12. Claims 2, 4, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- a.) Claim 2 recites the limitation of "0.1 xSSC, 0.1% SDS and 37°C" in line 5.

 This limitation is not supported by the specification as-filed. Page 10 of the specification recites "1x SSC, 0.1% SDS and 37°C". Claim 4 is included in this rejection as being dependent upon claim 2.

b.) Claim 18 recites the limitation of "0.1 xSSC, 0.1% SDS and 37°C" in line 2.

As set forth above, this limitation is not supported by the specification as-filed. Claim 19 is included in this rejection as being dependent upon claim 18.

The response filed May 15, 2007 points to the last paragraph of page 10 of the specification for support of "0.1x SSC, 0.1% SDS and 37°C". The last paragraph of page 10 does not provide support for 0.1x SSC. Applicant is required to point to the specific location in the specification that provides specific support for 0.1x SSC or amend the claims to remove the new matter.

- 13. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 14. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite for reciting "to produce polypeptide (a) or (b) or a polypeptide encoded by (c) or (d)". The limitations of (a) (b) (c) and/or (d) are not limitations in claim 5, from which claim 21 depends.

Conclusion

15. Claim 1 is in condition for allowance. Claims 2, 4, 5, 18, 19, and 21 are not allowed.

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

June 27, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER